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510(k) Summary

JUN 26 2009

General Information

Classification	Class II
Trade Name	Endoscopic Monopolar Scissors
Submitter	Apollo Endosurgery, Inc. 7000 Bee Cave Road Suite 350 Austin, Texas 78746 Tel: (512) 328-9990
Contact	Greg Mathison Vice President Regulatory

Indications for Use

The Apollo Endosurgery Endoscopic Monopolar Scissors are designed to cut, dissect, and cauterize tissue during flexible endoscopic procedures.

Predicate Devices

K011412	TeleMed Systems Flexible Endoscopic Scissors TeleMed Systems Inc.
K063485	Logic Laparoscopic Monopolar Scissors Surgical Innovations Group

Device Description

The Endoscopic Monopolar Scissors is comprised of a flexible metal shaft with a distal mounted scissors which is operated by a proximal handle. The proximal handle also has connections for a monopolar electrocautery source. The scissor blades function as standard scissors for mechanical cutting and for standard electrosurgical cutting, as required.

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Materials

All materials used in the manufacture of the Endoscopic Monopolar Scissors are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was completed and met all of the acceptance criteria. Testing included dimensional, visual, atraumatic tip, tortuous path, handle pull strength, resistivity, electrocautery and scissors performance.

Summary of Substantial Equivalence

The Endoscopic Monopolar Scissors is equivalent to the features of the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Mr. Gegory Mathison
Vice President, Regulatory Affairs
Apollo Endosurgery
7000 Bee Caves Road, Suite 350
AUSTIN TX 78746

Re: K090583
Trade/Device Name: Endoscopic Monopolar Scissors
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KGE
Dated: June 15, 2009
Received: June 17, 2009

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090583

Indications for Use

510(k) Number (if known): K090583

Device Name: Endoscopic Monopolar Scissors

Indications for Use: The Apollo Endosurgery Endoscopic Monopolar Scissors are designed to cut, dissect, and cauterize tissue during flexible endoscopic procedures.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090583